

REMARKS

1. *Status of claims*

After entry of the above amendment, claims 1-8, 10-17, 19-28, 30-33, 35, and 37 are pending and under consideration.

2. *Support for amendment*

The above amendment finds support in the specification and drawings at p. 1, lines 13-16; p. 4, lines 25-27; and Figure 1. No new matter has been added by this amendment.

3. *Claim rejections under 35 U.S.C. § 102*

First, the Examiner rejected claims 1-4, 6, 10-11, 13-14, and 16 under 35 U.S.C. § 102(e) as being anticipated by Michelson, US 6,537,320 ("Michelson"). After entry of the above amendment, Applicants traverse this rejection.

Michelson discloses a spinal fusion implant which comprises bone penetrating protrusions configured to penetrate the endplates of vertebrae and inserting the implant into a space defined by adjacent vertebrae and in part by an intervertebral disc annulus (Abstract and Figs. 3A-B). The skilled artisan will understand that configuring the bone penetrating protrusions of Michelson will involve imparting physical and structural properties to the protrusions to render them effective for penetrating vertebral endplates.

In contrast, the present claims recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises at least one thread configured to engage annular tissue, or methods for repairing an intervertebral

disc defect by use of the apparatus. The skilled artisan will understand that configuring the thread(s) will involve imparting physical and structural properties to the thread(s) to render it effective for engaging annular tissue. The physical and structural properties required to effectively engage annular tissue (primarily comprising fibrocartilage) would differ from those required to penetrate vertebral endplates (primarily comprising cortical bone without or with a layer of hyaline cartilage). The claimed apparatus is useful in performing a method for repairing an intervertebral disc defect, but would not be effective in performing a method for spinal fusion.

Michelson does not teach at least these elements of the present claims, and therefore cannot anticipate them. Applicants request this rejection of claims 1-4, 6, 10-11, 13-14, and 16 be withdrawn.

Second, the Examiner rejected claims 1-3, 6, 10-11, 13, and 16 under 35 U.S.C. §102(e) as being anticipated by Boyer, II, *et al.*, US 6,767,369 ("Boyer"). After entry of the above amendment, Applicants traverse this rejection.

Boyer discloses a plug for filling a vacancy in bone tissue (col. 3, lines 66-67; col. 4, lines 37-56), wherein the plug may be configured to be threadably received in a vacancy in bone tissue (col. 12, lines 42-45; Figure 3N). As noted above with respect to Michelson, the skilled artisan will understand that configuring the thread of Boyer will involve imparting physical and structural properties to the thread to render it effective for engaging bone tissue and not annular tissue.

As stated above, the present claims recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises at least one thread configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. The skilled artisan will understand that configuring the

thread(s) will involve imparting physical and structural properties to the members to render it effective for engaging annular tissue. The physical and structural properties required to effectively engage annular tissue would differ from those required to engage bone tissue. The claimed apparatus is useful in performing a method for repairing an intervertebral disc defect, but would not be effective in performing a method for filling a vacancy in bone tissue.

Boyer does not teach at least these elements of the present claims, and therefore cannot anticipate them. Applicants request this rejection of claims 1-3, 6, 10-11, 13, and 16 be withdrawn.

Third, the Examiner rejected claims 19-21, 25-28, 30-33, and 37 under 35 U.S.C. §102(e) as being anticipated by Bao et al., US 6,224,360 ("Bao"). After entry of the above amendment, Applicants traverse this rejection.

Bao discloses a plug for filling a defect in an intervertebral disc wherein the plug comprises an expanded end portion. However, the plug of Bao does not comprise at least one thread configured to engage annular tissue of an intervertebral disc, and thus Bao cannot teach use of a disc comprising a thread in a method of repairing a defect in an annular disc. Therefore, Bao does not teach every element of the present claims and this rejection of claims 19-21, 25-28, 30-33, and 37 should be withdrawn.

4. *Claim rejections under 35 U.S.C. § 103*

First, the Examiner rejected claims 5, 7-8, 12, 15, 17, and 35 under 35 U.S.C. §103(a) as being unpatentable over Michelson, as applied above, in view of Boyce et al., US 6,294,187 ("Boyce"). In light of the above amendment, Applicants traverse this rejection.

As discussed above, Michelson discloses a spinal fusion implant. Boyce discloses a load-bearing osteoimplant and a method for repairing bone using the same. Boyce does not overcome the deficiency of Michelson in teaching or suggesting the repair of an intervertebral disc defect, as discussed above. The combination of Michelson and Boyce neither teaches nor suggests the present claims, which recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises, *inter alia*, at least one thread configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. Therefore, Applicants request this rejection of claims 5, 7-8, 12, 15, 17, and 35 be withdrawn.

Second, the Examiner rejected claims 4-5, 7-8, 12, 14, 15, and 17 under 35 U.S.C. §103(a) as being unpatentable over Boyer in view of Boyce, as applied above. In light of the above amendment, Applicants traverse this rejection.

As discussed above, Boyer discloses a plug for filling a vacancy in bone tissue and Boyce discloses a load-bearing osteoimplant and a method for repairing bone using the same. Boyce does not overcome the deficiency of Boyer in teaching or suggesting the repair of an intervertebral disc defect, as discussed above. The combination of Boyer and Boyce neither teaches nor suggests the present claims, which recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises, *inter alia*, at least one thread configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. Therefore, Applicants request this rejection of claims 4-5, 7-8, 12, 14, 15, and 17 be withdrawn.

Third, the Examiner rejected claims 22-24 under 35 U.S.C. §103(a) as being unpatentable over Bao *et al.*, US 6,224,630 ("Bao") in view of Boyer, both as applied above. In light of the above amendment, Applicants traverse this rejection.

Bao discloses a device for insertion into a defect in the annulus of an intervertebral disc (Abstract). The device is preferred to comprise a non-biodegradable polymer, polyvinyl alcohol (PVA) (col. 5, lines 30-61). The device can comprise an expanded or enlarged end portion to prevent migration (col. 7, lines 61-67). As discussed above, Boyer discloses a plug for filling a vacancy in bone tissue.

The skilled artisan would have no motivation to combine the teachings of Bao and Boyer, as the two references are directed toward different therapies (i.e., repair of annular defect in an intervertebral disc vs. filling a void in bone). Even if, *arguendo*, such motivation existed, the combination would not guide the skilled artisan to use a plug having a thread for repairing an annular defect in an intervertebral disc. Bao teaches a plug for repair of a defect in the annulus of an intervertebral disc having an expanded or enlarged end portion for retention in the defect, but not having at least one thread disposed thereon. Boyer teaches a threaded device for filling a void in bone. Due to the aforementioned differences in the configuration of annulus- versus bone-engaging members, any attempt by the skilled artisan to incorporate the bone-engaging configuration of Boyer with the annular plug of Bao would result in an inoperable device and no reasonable expectation of success in achieving the same without undue experimentation. Therefore, Applicants request this rejection of 22-24 be withdrawn.

5. *Conclusion*

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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